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FDA's Focus Groups for the Project "Generic Drug Substitution in Special Populations"
Summary of Focus Groups Being Conducted

FDA's Center for Drug Evaluation and Research, Office of Generic Drugs needs to conduct focus groups to understand the alignment between clinical practice and labeled drug administration information discussed among practitioners and special patient populations in order to identify factors that raise issues for safety and effectiveness with generic substitution among special populations. Focus groups with individual physicians, pharmacists, and patients associated with targeted special populations are conducted to gain an in-depth understanding of the communication taking place between patients and their physicians and pharmacists about drug risks and instructions based on the unique needs of their identified population group.

What was the problem to be investigated? Bioequivalence studies that compare a reference formulation to an investigational generic formulation typically are conducted in healthy adult volunteers and occasionally are conducted in patients. Some patient populations have unique physical, biological, and physiological considerations that are not reflected by healthy volunteers or by the typical patient for whom a drug is indicated. Furthermore, there is a paucity of evidence on barriers to and patterns of generic substitution in special populations whose experiences with a drug are not represented by those in whom bioequivalence studies are conducted.

The method used to form the focus group. A marketing research firm, Baltimore Research, assists with recruitment and scheduling. Baltimore Research utilizes privately purchased marketing lists to recruit prescribers, pharmacists, patients, and/or pediatric patient proxies. Participant eligibility differs by group; participants meeting the eligibility requirements are contacted via telephone by Baltimore Research and asked if they wish to participate in the study provided they are able to during the designated date and time yet to be determined. Participants who are available and wish to participate in the focus group are mailed an electronic or hard copy of the informed consent letter within 48 hours of enrollment in the study and receive a reminder via email or phone of their scheduled focus group two days prior to their scheduled discussion date and time.

Burden imposed. A burden of approximately 28 hours in total is estimated based on 1-hour focus group discussions for a maximum of 28 participants across 4 types of participants in 3 focus groups. It should be noted that the anticipated total number of participants is 27, but we have included the maximum number of respondents and burden in order to allow the researchers the flexibility to include an additional pharmacist or prescriber to the Prescriber/Pharmacist focus group.